



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/764,161	
			Filing Date	January 23, 2004	
			First Named Inventor	John McMichael	
			Art Unit	1654 1655	
Examiner Name	To be assigned <i>Ranjit W. J. J.</i>				
Attorney Docket Number	13024/38629A				
Sheet	1	of	3		

U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code ² (if known)		
<i>W</i>	A1	5,240,846	08-31-1993	Collins <i>et al.</i>
<i>W</i>	A2	5,292,498	03-08-1994	Boucher, Jr.
<i>W</i>	A3	5,420,116	05-30-1995	Puchelle <i>et al.</i>
<i>W</i>	A4	5,470,838	11-28-1995	von Borstel <i>et al.</i>
<i>W</i>	A5	5,576,289	11-19-1996	McMichael, J.
<i>W</i>	A6	5,726,160	03-10-1998	McMichael, J.
<i>W</i>	A7	5,736,508	04-07-1998	McMichael, J.
<i>W</i>	A8	5,948,768	09-07-1999	McMichael, J. <i>et al.</i>
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Country
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)		
<i>W</i>	B1	WO 92/11016	07/09/92	WIPO
<i>W</i>	B2	WO 93/12240	06/24/93	WIPO
<i>W</i>	B3	WO 94/23048	10/13/94	WIPO
<i>W</i>	B4	WO 95/25800	09/28/95	WIPO
<i>W</i>	B5	WO 96/32138	10/17/96	WIPO
<i>W</i>	B6	WO 96/40059	12/19/96	WIPO
<i>W</i>	B7	WO 97/05195	02/13/97	WIPO

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>W</i>	C1	Alton, E.W.F.W. <i>et al.</i> , "Noninvasive liposome-mediated gene delivery can correct the ion transport defect in cystic fibrosis mutant mice," <i>Chemical Abstracts</i> , 119:62 (1993) (ABSTRACT 217089w)	
<i>W</i>	C2	Badesch <i>et al.</i> , "Continuous Intravenous Epoprostenol for Pulmonary Hypertension Due to the Scleroderma Spectrum of Disease, A Randomized, Controlled Trial," <i>Ann. Intern. Med.</i> , 132:425-434 (2000).	
<i>W</i>	C3	Baker, R.C., "Pitfalls in Diagnosing Acute Otitis Media," <i>Pediatric Annals</i> , 20:591-593; 596-598 (1991).	
<i>W</i>	C4	Barst <i>et al.</i> , "A Comparison of Continuous Intravenous Epoprostenol (Prostacyclin) With Conventional Therapy for Primary Pulmonary Hypertension," <i>N. Eng. J. Med.</i> , 334:296-301 (1996).	

Examiner Signature	<i>John McMichael</i>	Date Considered	09/14/06
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/764,161
		Filing Date	January 23, 2004
		First Named Inventor	John McMichael
		Group Art Unit	1054 1655
		Examiner Name	To be assigned <i>Richard W. ...</i>
		Attorney Docket Number	13024/38629A
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~	C5	Berkow, R. (Ed.), The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, N.J. pp. 600-602 (1992).	
~	C6	Berman, S., "Otitis Media in Developing Countries," <i>Pediatrics</i> , 96:126-131(1995).	
~	C7	Canonico, A.E. et al., "Expression Of A Cmv Promoter Driven Human A-1 Antitrypsin Gene In Cultured Lung Endothelial Cells And In The Lungs Of Rabbits," <i>Clin. Res.</i> , 39(2): 219A (1991).	
~	C8	Carman et al., "A Primary Care Approach to the Patient with Claudication," <i>Am. Fam. Physician</i> , 61:1027-1032 (2000).	
~	C9	Cunningham, M.W., "Pathogenesis of Group A Streptococcal Infections," <i>Clin. Microbiol.</i> 13:470-511 (2000).	
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~	C11	Dawson et al., "Cilostazol Has Beneficial Effects In Treatment of Intermittent Claudication," <i>Circulation</i> , 98:678-686 (1998).	
~	C12	DeGraves et al., "Economics of Mastitis and Mastitis Control," <i>The Veterinary Clinics of North America-Food Animal Practice Update on Bovine Mastitis</i> , 9:421-434 (1993).	
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~	C16	Gardner et al., "Exercise Rehabilitation Programs for the Treatment of Claudication Pain: A Meta Analysis," <i>JAMA</i> , 274:975-980 (1995).	
~	C17	Goldhaber et al., "Low-Dose and Subsequent Peripheral Arterial Surgery in the Physicians' Health Study," <i>Lancet</i> , 340:143-145 (1992).	
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~	C19	Hood et al., "Management of Intermittent Claudication with Pentoxifylline: Meta-Analysis of Randomized Controlled Trials," <i>CMAJ</i> , 155:1053-1059 (1996).	
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~	C24	Ledley, F.D., "Non-viral gene therapy," <i>Current Opinion in Biotechnology</i> , 5: 626-636 (1994).	
~	C25	Ledley, F.D., "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products," <i>Human Gene Therapy</i> , 6: 1129-1144 (September, 1995).	
~	C26	Marshall, E., "Gene Therapy's Growing Pains," <i>Science</i> , 269: 1050-1055 (1995).	

Examiner Signature	<i>[Signature]</i>	Date Considered	09/14/06
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			Filing Date	January 23, 2004
			First Named Inventor	John McMichael
			Group Art Unit	1654 1655
			Examiner Name	To be assigned <i>Handal / W. W. W.</i>
			Attorney Docket Number	13024/38629A
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~	C27	Patterson et al., "Value of a Supervised Exercise Program for the Therapy of Arterial Claudication," <i>J. Vasc. Surg.</i> , 25:312-319 (1997).	
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~	C29	Rosenfeld, M.A. et al., "Adenovirus-Mediated Transfer of a Recombinant α1-Antitrypsin Gene to the Lung Epithelium in Vivo," <i>Science</i> , 252: 431-434(1991).	
~	C30	Rosenfeld, J. et al., "Acute Otitis Media in Children," <i>Primary Care; Clinics in Office Practice</i> , 23(4):677-686(1996).	
~	C31	Ruiz et al., "Streptolysin O and Adherence Synergistically Modulate Proinflammatory Responses of Keratinocytes to Group A Streptococci," <i>Mol. Microbiol.</i> 27:337-346 (1997).	
~	C32	Schrager et al., "Hyaluronic Acid Capsule Modulates M Protein-Mediated Adherence and Acts as a Ligand for Attachment of Group A <i>Streptococcus</i> to CD44 on Human Keratinocytes," <i>J. Clin. Investig.</i> 101:1708-1716 (1998)	
~	C33	Silver et al., "Evaluation and Management of Scleroderma Lung Disease Using Bronchoalveolar Lavage," <i>Am. J. Med.</i> , 88:470-476 (1990).	
~	C34	Unemori et al., "Relaxin Modulates Synthesis and Secretion of Procollagenase and Collagen by Human Dermal Fibroblasts," <i>J. Biol. Chem.</i> , 265:10681-10685 (1990).	
~	C35	Visa et al., "The Value of Fasciectomy in the Surgical Approach of the Dupuytren's Disease," <i>Romanian Journal of Hand and Reconstructive Microsurgery</i> , 5:9-13 (2000).	
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~	C37	White et al., "Cyclophosphamide is Associated with Pulmonary Function and Survival Benefit in Patients with Scleroderma and Alveolitis," <i>Ann. Intern. Med.</i> , 132:947-954 (2000).	
~	C38	Siebold et al., "Recombinant Human Relaxin in the Treatment of Scleroderma, A Randomized, Double-Blind, Placebo-Controlled Trial," <i>Ann. Intern. Med.</i> , 132:871-879 (2000).	
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~	C42	Askanas et al., "A New Program for Investigating Adult Human Skeletal Muscle Grown Aneurally in Tissue Culture," <i>Neurology</i> , 25:58-67 (1975).	

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				Application Number	10/764,161-Conf. #8158
				Filing Date	January 23, 2004
				First Named Inventor	John McMichael
				Art Unit	1654 1655
				Examiner Name	Not Yet Assigned <i>RANDALL WILSON</i>
Sheet	1	of	1	Attorney Docket Number	13024/38629A

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
<i>W</i>	A	US-6,096,721	08-01-2000	McMichael	
<i>W</i>	B	US-6,303,127	10-16-2001	McMichael et al.	
<i>W</i>	C	US-6,447,820	09-10-2002	Niazi	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>W</i>	D	International Search Report corresponding to International Patent Application Serial No. PCT/US04/01887 dated August 26, 2004, 2 pages.	

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